REMARKS

Status of the Claims

The present Office Action addresses and rejects claims 7-28 and 41-44. Applicant respectfully requests reconsideration in view of the remarks herein.

Amendments to the Claims

Claim 7 is amended to recite that the at least one through hole formed in the first pledget has a minimum diameter greater than a maximum diameter of the suture. Claim 11 is amended to recite that the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a second position substantially perpendicular to the first position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in said tissue. Support for these amendments can be found throughout the specification and drawings, such as in Figures 1 and 2 and in paragraphs [0035] and [0036] of the published application. No new matter is added.

Rejections Pursuant to 35 U.S.C. § 102

Claims 11-13, 15, and 22-26 are rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,669,473 ("Richards"). Applicant respectfully disagrees.

Independent claim 11 recites a tissue fixation device including a suture suitable for in vivo placement in a human or animal body, a first biocompatible securing element connected to a first portion of the suture, and a second biocompatible securing element connected to a second portion of the suture. Each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a second position substantially perpendicular to the first position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in the human or animal tissue. The tissue fixation device also includes a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue.

Richards does not teach or suggest that the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a *second position substantially perpendicular to the first position when the tissue fixation device is deployed* that inhibits each securing element from passing through the respective hole formed in said tissue. Indeed, Richards explicitly teaches the impossibility of such in tissue for its fastener heads (15B, 315), which the Examiner likens to securing elements.

In Richards, the fastener heads (15B, 315) in a normal position are attached "substantially perpendicular" to their respective filaments (10, 310). FIGS. 1, 8, and 10; col. 3, lines 25-29. During deployment, a fastener head is in a first position that is bent ninety degrees from its normal position and delivered into tissue through a sheath (105) of a deployment tool (100). FIGS. 2, 3, 11, and 12; col. 4, lines 19-33. Following deployment through a hole in tissue, the head digs into surrounding tissue and moves from the first position in an "*attempt* to resume its normal position substantially perpendicular to the adjoining length of filament of the fastener." Col. 4, lines 45-64 (Emphasis added). However, because of the head's size relative to the hole in the tissue, the head does not move to a *second position substantially perpendicular to the first position* but instead "return[s] only a fraction of the way back to its original perpendicular position." Col. 4, line 64 to col. 5, line 6; col. 8, line 57 to col. 9, line 1. Thus, it is clear that the fastener heads (15B, 315) are not rotatable from a first position to a second position that is substantially perpendicular to the first position when the device is deployed in tissue.

Accordingly, independent claim 11, as well as claims 12, 13, 15, and 22-26 which depend therefrom, distinguish over Richards and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. § 103

Richards in view of McQuilkin

Claims 7-10, 18-21, and 41-44 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,219,359 ("McQuilkin"). Applicant respectfully disagrees.

Claims 7-10, 42, and 43

Independent claim 7 recites a tissue fixation device including a suture and first and second bioimplantable pledgets. The first pledget has at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture, a first portion of the suture passing through the at least one through hole in the first pledget and a second portion of the suture configured to inhibit the second portion from passing through the at least one through hole in the first pledget. The second pledget has at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The tissue fixation device also includes a first bioimplantable securing element connected to a portion of the suture and being rotatable from a first orientation in which the securing element is oriented at least substantially parallel to the at least one through hole formed in the first pledget and the second pledget, to a second orientation in which the securing element is oriented at least substantially perpendicular to the at least one through hole in the second pledget. The suture, the first and second pledgets, and the first securing element are effective to fix adjacent layers of living tissue.

Richards does not teach or suggest a pledget having a minimum diameter greater than a maximum diameter of the suture. The minimum diameter of the hole in the washer (40B), which the Examiner likens to a pledget, is clearly *less than* the maximum diameter of the fastener's filament (310) because the ribs (35B) that are part of the filament (310) must be larger than the washer's hole so as to secure the fastener (5B) therein. McQuilkin is only relied on for various other features of the claimed invention and fails to remedy the deficiencies of Richards, at least because even if it was combined with Richards as suggested by the Examiner, Richards' ribs (35B) would still have to be larger than any pledget through hole for the fastener and pledget to be operable.

Accordingly, for at least these reasons, independent claim 7, as well as claims 9-10, 42, and 43 which depend therefrom, distinguish over Richards and McQuilkin, taken alone or in combination, and represent allowable subject matter.

Claims 18-21

As explained above, Richards does not teach or suggest independent claim 11. McQuilkin is relied on for various other features of the claimed invention and does not remedy the deficiencies of

Richards. Therefore, claims 18-21, which ultimately depend from claim 11, distinguish over Richards and McQuilkin, either taken alone or together, and represent allowable subject matter.

Claims 41 and 44

Independent claim 41 recites a tissue fixation device including a suture and first and second bioimplantable pledgets. The first pledget has a plurality of through holes formed therein, the suture passing through the through holes. The second pledget has a plurality of through holes formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The tissue fixation device also includes a first bioimplantable securing element being coupled to the suture and having a sharp tip and a proximal end configured for removable attachment to an instrument, and a second bioimplantable securing element being coupled to the suture and having a sharp tip and a proximal end configured for removable attachment to an instrument. The suture, the first and second pledgets, and the first and second securing elements are effective to fix adjacent layers of living tissue.

Richards does not teach or suggest a first or second securing element having a *proximal end configured for removable attachment* to an instrument. In Richards, a fastener head is deployed using the deployment tool (100) by positioning the head inside the sheath (105) and *sliding* the head therethrough. Therefore, the head is not configured to be attached to the tool (100) in any way, much less removably attached thereto. Moreover, claim 41 requires that the *proximal end* of the securing element be configured for removable attachment to the instrument. Richards's fastener head is smooth and bar-like with flat, angled terminal ends. Neither of the terminal ends are configured to be removably attached to the tool (100). In contrast, Applicant discloses a securing element having a proximal end that is configured to be removably attached to an instrument, e.g., the securing element (66) of Figure 11 having a proximal end (72) with a nub (76) that is slidably receivable in a slot (78) of a deployment instrument (74). Richards simply does not in any way teach or suggest the claimed invention.

McQuilkin does not remedy the deficiencies of Richards as McQuilkin is relied on for various other features of the claimed invention and fails to disclose a securing element, much less one that is configured for removable attachment to an instrument.

Accordingly, for at least these reasons, independent claim 41, as well as claim 44 which depends therefrom, distinguish over Richards and McQuilkin, taken alone or in combination, and represent allowable subject matter.

Richards

Claim 15 is rejected pursuant to 35 U.S.C. § 102(b) as indicated above, or in the alternative, pursuant to 35 U.S.C. § 103(a) as being obvious over Richards. As explained above, Richards does not teach or suggest independent claim 11. Therefore, claim 15, which ultimately depends from claim 11, distinguishes over Richards and represents allowable subject matter.

Richards in view of Bonutti

Claims 16, 17, 27, and 28 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,845,645 ("Bonutti"). As explained above, Richards does not teach or suggest independent claim 11. Bonutti is relied on for various dependent claim features and does not remedy the deficiencies of Richards. Therefore, claims 16, 17, 27, and 28, which ultimately depend from claim 11, distinguish over Richards and Bonutti, either taken alone or together, and represent allowable subject matter.

Conclusion

Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Dated: December 4, 2008

Respectfully submitted,

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